

デジタルヘルス関連規制文書の抽出と 新規文書のモニタリング方法

Cortellis Regulatory Intelligence - デジタルヘルス関連規制文書の検索例

手順1. "eHealth" Topicフィルターを使用してデジタルヘルス関連規制文書をリストアップする

1. 検索ボックス下の"Filter"から

"Topic" > "eHealth"を選択して"Apply"で確定

The screenshot shows the search interface with various filters at the top. The 'Topic' filter is selected and highlighted with a blue box. Below the filters, a list of topics is shown, with 'eHealth (6647)' highlighted with a blue box. A large blue arrow points downwards to the next step.

2. 必要に応じて検索キーワードやフィルター項目を追加し、

"Search"をクリックして検索を実行します

(ここでは"Country/Region" > "USA"フィルターを追加)

The screenshot shows the search interface with the 'Country/Region' filter set to 'USA' and the 'Topic' filter set to 'eHealth'. A large blue arrow points upwards to the next step. A red box highlights the 'Search' button, which is being clicked.

3. "Topic"の索引である"eHealth"が付与された、

デジタルヘルス関連の米国の文書がリストアップされます

The screenshot shows the search results page with 4,039 results. The results are sorted by relevance. One document is listed: '510(k) Premarket Notification K252007: BLINESLIDE, 06-Oct-2025'. The document details are shown: On October 06, 2025, FDA cleared 510(k) premarket notification K252007 for BLINESLIDE. Device Name: BLINESLIDE. The document is from the USA and was updated on 17-Nov-2025.

eHealthの索引付け対象例：Mobile medical applications, Telemedicine, Artificial Intelligence, Electronic Health Record, Wireless Medical Device, Software as a Medical Device等に関する規制文書

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手順2. "Refine Search"で更にキーワードやフィルターを追加して絞り込み可能

4. 検索キーワードを追加してみます

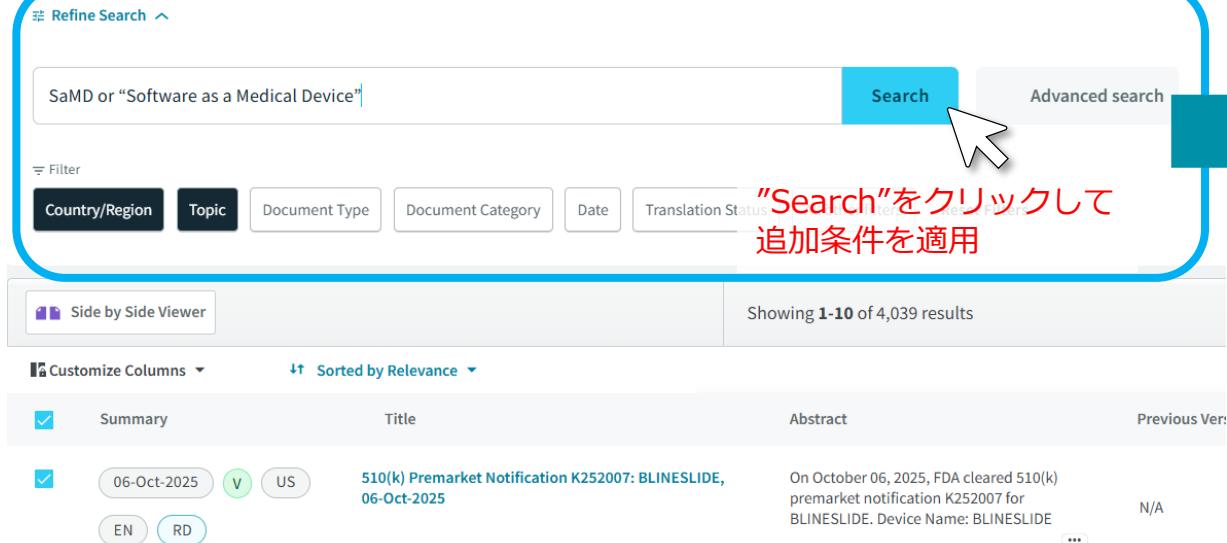
例 : SaMD or "Software as a Medical Device"

Regulatory > All Results

4,039 results

Switch to Comparison Tables

Refine Search機能



Refine Search

SaMD or "Software as a Medical Device"

Search

Advanced search

Search"をクリックして追加条件を適用

Side by Side Viewer

Showing 1-10 of 4,039 results

Customize Columns

Sorted by Relevance

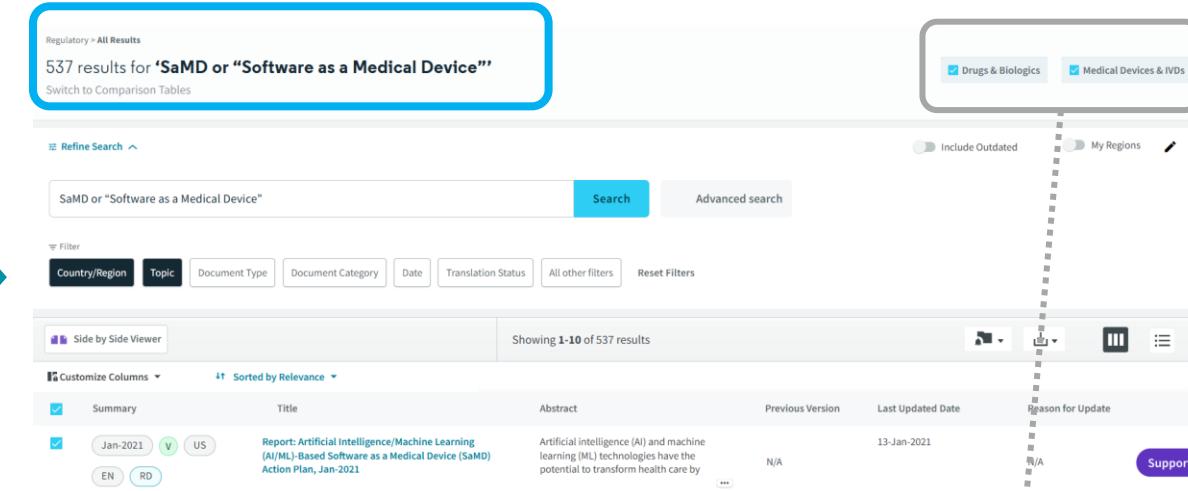
Summary	Title	Abstract	Previous Ver:
<input checked="" type="checkbox"/> 06-Oct-2025 V US	510(k) Premarket Notification K252007: BLINESLIDE, 06-Oct-2025	On October 06, 2025, FDA cleared 510(k) premarket notification K252007 for BLINESLIDE. Device Name: BLINESLIDE	N/A

"eHealth" Topicの収録文書数 (2025年11月時点)

- Drugs & Biologics: 約2,137
 - Medical Devices & IVDs: 約5,042
- (両モジュールでの重複収録あり、また購読されている国・地域によって閲覧できる文書数に違いがあります)

5. 検索結果の絞り込みが完了しました

4,039件→537件



Regulatory > All Results

537 results for 'SaMD or "Software as a Medical Device"'

Switch to Comparison Tables

Refine Search

SaMD or "Software as a Medical Device"

Search

Advanced search

Filter

Country/Region Topic Document Type Document Category Date Translation Status All other filters Reset Filters

Side by Side Viewer

Showing 1-10 of 537 results

Customize Columns

Sorted by Relevance

Summary	Title	Abstract	Previous Version	Last Updated Date	Reason for Update
<input checked="" type="checkbox"/> Jan-2021 V US	Report: Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan, Jan-2021	Artificial intelligence (AI) and machine learning (ML) technologies have the potential to transform health care by	N/A	13-Jan-2021	N/A

Drugs & Biologics

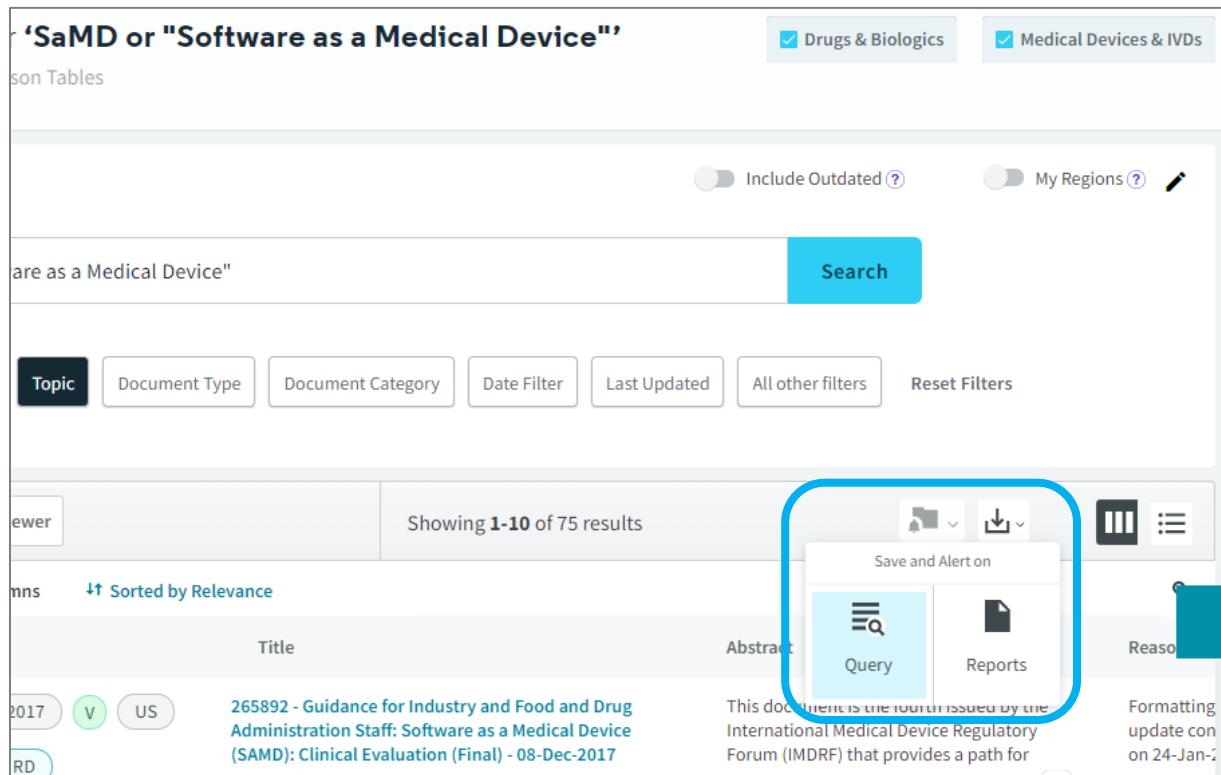
Medical Devices & IVDs

さらに検索結果に表示される文書のカテゴリを"Drugs & Biologics"または"Medical Devices & IVDs"関連の文書に絞ることも可能です (両モジュールをご利用中のユーザー様のみ)

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手順3. 検索条件にアラートを設定して新たな規制文書の出現をモニタリング (Save and Alert on Query)

6. 検索条件に合致する新たな規制文書の収録をモニターするためアラートを設定します



'SaMD or "Software as a Medical Device"'

Drugs & Biologics Medical Devices & IVDs

Include Outdated My Regions

Search

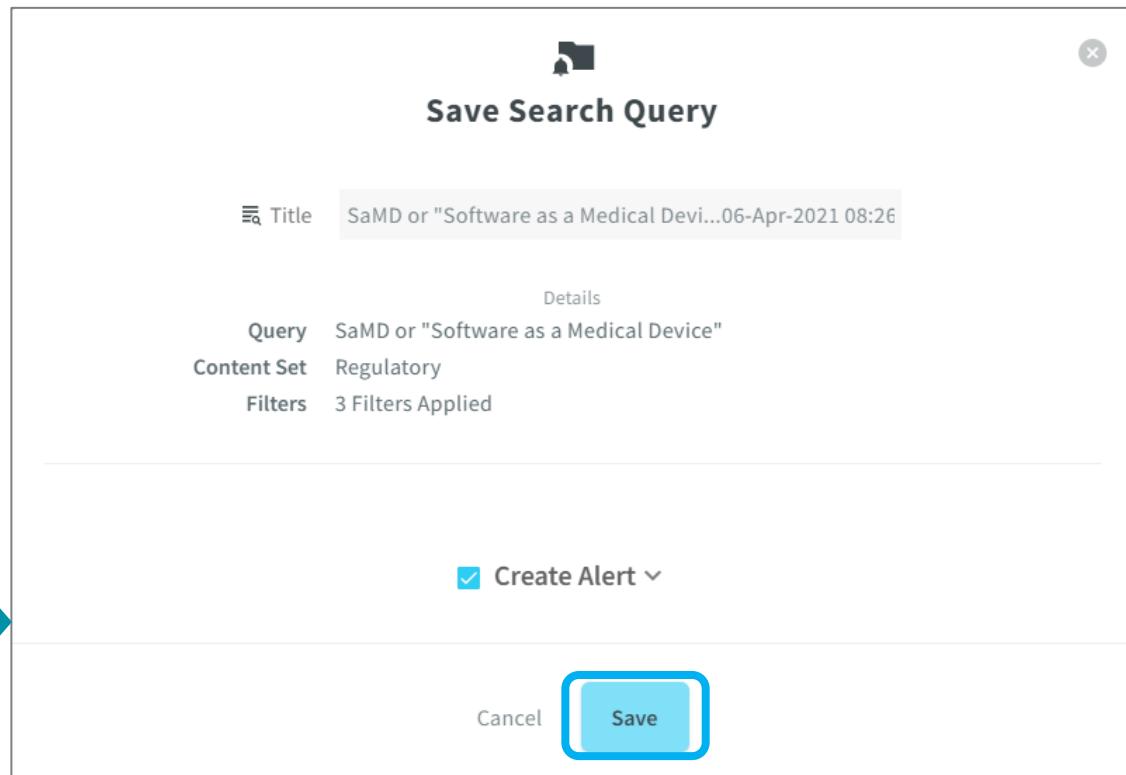
Topic Document Type Document Category Date Filter Last Updated All other filters Reset Filters

Showing 1-10 of 75 results

Title	Abstract	Reason
265892 - Guidance for Industry and Food and Drug Administration Staff: Software as a Medical Device (SaMD): Clinical Evaluation (Final) - 08-Dec-2017	This document is the fourth issued by the International Medical Device Regulatory Forum (IMDRF) that provides a path for...	Formatting update con...

検索結果画面のベルのアイコンをクリックしてSave and Alert onメニューから"Query"を選択します。

7. アラート条件を確認し"Save"で設定を完了すると、今後、検索条件に合致する新たな文書の出現をメールで通知します



Save Search Query

Title: SaMD or "Software as a Medical Devi...06-Apr-2021 08:26

Query: SaMD or "Software as a Medical Device"

Content Set: Regulatory

Filters: 3 Filters Applied

Create Alert

Save

"Save"をクリックするとすぐにDaily Alertの設定が完了します。"Create Alert"の右側の▼をクリックすると、アラート頻度等の詳細設定が可能です。